

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA,
EX REL. [under seal]

- and -

[under seal]

Plaintiffs

v.

[under seal]

Defendant.

2003 JUL 16 P 3:30
U.S. DISTRICT COURT
(FILED BY CAMERA AND UNDER
SEAL)

CIVIL ACTION NO. _____

(JURY TRIAL DEMANDED)

02 - 11436 RGS

COMPLAINT

(False Claims Act)

FILED FEE PAID:
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AMOUNT \$ 150.00
BY DEPT CLK [signature]
DATE 7/17/02

SEALED

SEALED

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

**UNITED STATES OF AMERICA,
EX REL. DEBORAH MAGUIRE**

- and -

**DEBORAH MAGUIRE
c/o Christopher B. Mead, Esquire
London & Mead
1225 19th St., N.W., Suite 320
Washington, D.C. 20036**

Plaintiffs

v.

**OMNICARE, INC.
1600 RiverCenter II
100 East RiverCenter Blvd.
Covington, KY 41011**

Defendant.

FILED IN CAMERA AND UNDER SEAL

02 - 11436 RGS

CIVIL ACTION NO.

JURY TRIAL DEMANDED

COMPLAINT

This lawsuit is based on a scheme by the Defendant and its subsidiaries to violate the Anti-Kickback Act, 42 U.S.C. § 1320A-7b(b)(2), by offering the services of pharmacy consultants at below market rates to nursing homes, skilled nursing facilities, and other long term care facilities ("LTCFs"). The offers of these pharmacy consultant services at below market rates induce LTCFS to enter into contracts allowing Omnicare, Inc. and its subsidiaries (collectively "Omnicare") to provide drug products to patients of those LTCFs, and to bill Medicaid and other payers for those drugs. Omnicare's pharmacy consultants review all medications taken by LTCF

patients and recommend different medications that result in greater profits to Omnicare, and, upon information and belief, also result in higher bills to Medicaid in many instances. Upon information and belief, Omnicare also followed a practice of falsely and fraudulently billing for more expensive, name brand drugs when it had actually provided generic versions of those drugs. Plaintiff Deborah Maguire, by undersigned counsel, and acting on behalf of and in the name of the United States of America, brings this civil action under the qui tam provisions of the False Claims Act, and alleges as follows:

Jurisdiction and Venue

1. This is a civil action by Plaintiff Deborah Maguire, acting on behalf of and in the name of the United States, against Defendant Omnicare, Inc. under the False Claims Act, 31 U.S.C. 3729-33 (1988). This Court has jurisdiction over this lawsuit pursuant to 28 U.S.C. 1345 and 31 U.S.C. 3732(a).

2. Omnicare has offices and a distribution center in Peabody, Massachusetts. Omnicare causes its wholly-owned subsidiary in Massachusetts, Omnicare Pharmacy of Massachusetts LLC, to follow Omnicare's corporate policies. Omnicare thus transacts business in the State of Massachusetts. Venue in this District is proper pursuant to 28 U.S.C. 1391(c) and 31 U.S.C. 3732(a).

Parties

3. Plaintiff Deborah Maguire started working for Omnicare, Inc. in October of 2000. She was hired to market and manage home hemodialysis programs offered by Omnicare to long-term care facilities ("LTCFs").

4. Defendant Omnicare, Inc., is a Delaware corporation with its headquarters at 1600 RiverCenter II, 100 East RiverCenter Blvd., Covington, Kentucky 41011. It is the nation's largest provider of pharmacy services to LTCFs. Omnicare serves more than 729,500 residents in 9,800 LTCFs such as nursing homes, skilled nursing facilities, assisted living communities, and other institutional healthcare settings in 45 states. Omnicare owns the following subsidiaries: AAHS Acquisition Corp., Accu-Med Services, Inc., ACP Acquisition Corp., AMC - New York, Inc., AMC - Tennessee, Inc., Anderson Medical Services, Inc., Bach's Pharmacy (East) Inc., Bach's Pharmacy Services, LLC, Badger Acquisition LLC, Badger Acquisition of Brooksville LLC, Badger Acquisition of Kentucky LLC, Badger Acquisition of Minnesota LLC, Badger Acquisition of Ohio LLC, Badger Acquisition of Orlando LLC, Badger Acquisition of Tampa LLC, Badger Acquisition of Texas LLC, Bio-Pharm International, Inc., BPNY Acquisition Corp., BPTX Acquisition Corp., Campo's Medical Pharmacy, Inc., Care Pharmaceutical Services, Inc., Catapharm Corp., CHP Acquisition Corp., CIP Acquisition Corp., CompScript - Boca, Inc., CompScript - Mobile, Inc., CompScript, Inc., CP Acquisition Corp., Creekside Managed Care Pharmacy, Inc., CTLP Acquisition Corp., D & R Pharmaceutical Services, Inc., Dixon Pharmacy, Inc., Electra Acquisition Corp., Enloe Drugs, Inc., Euro Bio-Pharm Clinical Services, Inc., Evergreen Pharmaceutical of California, Inc., Evergreen Pharmaceutical, Inc., Hardardt Group, Inc., Heartland Repack Services LLC, HMIS, Inc., Home Care Pharmacy, Inc., Home Pharmacy Services, Inc., Howard's Pharmacy, Inc., Hytree Pharmacy, Inc., Interlock Pharmacy Systems, Inc., JHC Acquisition, Inc., Konsult, Inc., Langsam Health Services, Inc., Langsam Medical Products, Inc., Lawrence Medical Supply, Inc., LCPS Acquisition, LLC, Lo-Med Prescription Services, Inc., LPI Acquisition Corp., Managed Healthcare, Inc., Med World Acquisition Corp., Medical Arts Health Care, Inc., Medical Services Consortium, Inc., MOSI Acquisition Corp.,

Nihan & Martin, Inc., NIV Acquisition Corp., North Shore Pharmacy Services, Inc., OCR Services Corporation, OCR-RA Acquisition Corp., OFL Corp., Omnibill Services LLC, Omnicare Air Transport Services, Inc., Omnicare Clinical Research, Inc., Omnicare Clinical Research, LLC, Omnicare CR, Inc., Omnicare Holding Company, Omnicare Management Company, Omnicare Pennsylvania Med Supply, LLC, Omnicare Pharmaceuticals, Inc., Omnicare Pharmacies of Pennsylvania East, LLC, Omnicare Pharmacies of Pennsylvania West, Inc., Omnicare Pharmacies of the Great Plains Holding Company, Omnicare Pharmacy and Supply Services, Inc., Omnicare Pharmacy of Colorado, LLC, Omnicare Pharmacy of Maine Holding Company, Omnicare Pharmacy of Maine LLC, Omnicare Pharmacy of Massachusetts LLC, Omnicare Pharmacy of Nebraska LLC, Omnicare Pharmacy of the Midwest, Inc., Omnicare Pharmacy of South Dakota LLC, Omnicare Pharmacy of Tennessee LLC, Omnicare.com, Inc., PBM-Plus, Inc., PCI Acquisition, LLC, Pharmacon Corp., Pharmacy Associates of Glens Falls, Inc., Pharmacy Consultants, Inc., Pharm-Corp of Maine LLC, Pharmed Holdings, Inc., PRN Pharmaceutical Services, Inc., Resource Biometrics, Inc., Roeschen's Healthcare Corp., Royal Care of Michigan LLC, SHC Acquisition Co., LLC, Shore Pharmaceutical Providers, Inc., Southside Apothecary, Inc., Specialized Home Infusion of Michigan, LLC, Specialized Patient Care Services, Inc., Specialized Pharmacy Services, Inc., Sterling Healthcare Services, Inc., Superior Care Pharmacy, Inc., Swish, Inc., TCPI Acquisition Corp., THG Acquisition Corp., Three Forks Apothecary, Inc., UC Acquisition Corp., Value Health Care Services, Inc., Value Pharmacy, Inc., Vital Care Infusions Supply, Inc., Weber Medical Systems, Inc., Westhaven Services Co., Williamson Drug Company, Incorporated, Winslow's Pharmacy. Upon information and belief, Omnicare also has ownership interests in other subsidiaries not listed above. Omnicare and its subsidiaries, known and unknown, shall be referred to as "Omnicare."

Factual Allegations

5. 42 C.F.R. 483.60(a) requires LTCFs to "provide pharmaceutical services (including procedures that assure the accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals) to meet the needs of each resident." 42 C.F.R. 483.60(b) and (c) provide that LTCFs

must employ or obtain the services of a licensed pharmacist who-- (1) Provides consultation on all aspects of the provision of pharmacy services in the facility; (2) Establishes a system of records of receipt and disposition of all controlled drugs in sufficient detail to enable an accurate reconciliation; and (3) Determines that drug records are in order and that an account of all controlled drugs is maintained and periodically reconciled.

(c) Drug regimen review.

(1) The drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist. (2) The pharmacist must report any irregularities to the attending physician and the director of nursing, and these reports must be acted upon.

6. Omnicare's core business is to provide pharmaceutical services to LTCFs.

Omnicare offers to take over all drug procurement, services, and billing for LTCFs. Omnicare offers the regulatorily-required pharmaceutical consultant services to LTCFs if those LTCFs allow Omnicare pharmacies to provide all drugs and certain other products to the patients of the LTCFs. Omnicare buys drugs from manufacturers, distributes the drugs to the LTCFs, and bills Medicaid and other payers for the drugs.

7. The Medicaid Program provides federal funds to the states to assist the poor, elderly, and disabled to receive medical care, prescription and non-prescription drugs, and related services. States may elect to opt in or out of the Medicaid Program. States that opt into the program must submit a State Plan ("Medicaid State Plan") to the United States Department of Health and Human Services ("DHHS") for approval, describing the policies and methods used to

set reimbursement rates for each type of service included in the program. The provision of drugs, pharmaceuticals, and related services are one such type of service. Both the Medicaid State Plan and any amendments must meet federal requirements. 42 U.S.C. 1396a(a) and (b); 42 C.F.R. 430.10, 430.12.

8. Medicaid prescription drug reimbursement to pharmacies like Omnicare consists of two components: a formula to cover the cost of the prescription drug product and a dispensing fee. The drug product component cost is the cost of the drug as determined by a Medicaid formula which estimates the acquisition cost. Federal law requires that the dispensing fee paid to pharmacies be reasonable. 42 C.F.R. 447.331(b)(1).

9. Medicaid State Plans set reimbursement amounts for drug products, and also set dispensing fees.

10. Medicaid covers a large percentage of patients in LTCFs. Omnicare's Securities and Exchange Commission ("SEC") filings indicate that 44% of its reimbursements for pharmaceutical services come from Medicaid, with 3% coming from Medicare. Omnicare's Pharmacy Services segment recorded sales of over two billion dollars for the year ended December 31, 2001, indicating that Omnicare submits millions of claims to Medicaid each year, and receives hundreds of millions of dollars in reimbursements from the federal government each year.

11. Omnicare's SEC filings state that Omnicare's consolidated gross profit as a percentage of sales in the year ending December 31, 2001, was 26.8%. The only way Omnicare can make such profits on its core pharmaceutical services business is to ensure that Omnicare acquisition costs and distribution expenses stay significantly below the reimbursement levels

Omnicare receives for drugs. The difference between Omnicare's acquisition costs versus reimbursement levels for particular drugs will be referred to hereafter as "the spread."

12. Omnicare's offer to provide regulatorily-required pharmacy consultant services to LTCFs is a crucial part of Omnicare's business plan. The cost of paying a pharmacist to review medications of each patient every month, and to supervise drug distribution, is ordinarily a significant expense to LTCFs. Omnicare offers pharmaceutical services to LTCFs at below market rates as an inducement for LTCFs to sign pharmacy services contracts with Omnicare. Omnicare's offer of pharmacy consultant services at below market rates, coupled with its offer to take over drug procurement, distribution, and billing, has allowed Omnicare to obtain pharmacy services contracts with thousands of LTCFs, to the point that Omnicare now serves more than 729,500 residents in 9,800 LTCFs. Omnicare has also built its patient base by acquiring other pharmacy services companies that market to nursing homes.

13. Omnicare's offer of pharmacy consultant services at below market rates as an inducement for LTCFs to sign pharmacy services contracts is a violation of the Anti-Kickback Act, 42 U.S.C. § 1320A-7b(b)(2). The Anti-Kickback Act forbids health care providers from offering goods or services at below-market rates as an inducement for referrals, recommendations, or arranging health care services reimbursable under Federal health care programs. The statute specifically provides:

- (2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person –
 - (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

- (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a crime.

14. Once Omnicare's pharmacy consultants are in place at LTCFs, those consultants are in an advantageous position to recommend medications for patients of the LTCF. Regulations require the pharmacy consultants to review all medications prescribed for LTCF patients on a monthly basis, giving the consultants access to complete medication information for each patient. Physicians understand that such pharmacy consultants are expected to make recommendations to change prescriptions for patients if better or less expensive medications are available. Physicians are frequently inclined to follow recommendations from such consultants if they sound reasonable on their face. Physicians frequently are not aware of the reimbursement levels for drugs, and are inclined to accept recommendations from consultants when consultants say that the recommendations are based on cost considerations.

15. Omnicare has adopted and published a book of "Omnicare Guidelines," which rank specific drugs in therapeutic classes as preferred, acceptable or unacceptable. The Omnicare Guidelines provide cost information using a system of one to four stars for each drug. Upon information and belief, such general classifications on cost allow Omnicare to conceal reimbursement differentials between drugs that have the same number of "stars" in the cost rankings.

16. In addition to the "Omnicare Guidelines" for recommending drugs, Omnicare also engages in periodic "fax campaigns," where Omnicare headquarters sends faxes for distribution

to all its pharmacy consultants recommending a certain drug for particular disease conditions. For example, in November, 2001, Omnicare identified all patients it serviced who were on “conventional” antipsychotic medications, such as haloperidol, mesoridazine, thioridazine, and fluphenazine. Omnicare then faxed or called the physicians for each of those patients, recommending that the patients be switched to Risperdal, an “atypical” antipsychotic medication. Omnicare then required all its pharmacy consultants to follow up with doctors to recommend Risperdal. Omnicare said in a fax to its pharmacy consultants that “[i]t is imperative that each and every resident on a conventional antipsychotic be re-evaluated for appropriate conversion to an atypical antipsychotic, with Risperdal being the more cost effective GPCG ‘preferred’ alternative.”

17. Omnicare hires pharmacists as independent contractors to provide pharmacy consultant services to LTCFs. On information and belief, Omnicare pays those pharmacy consultants more than it charges LTCFs for their services. On information and belief, Omnicare evaluates and compensates its pharmacy consultants based on the consultants’ ability to successfully recommend drugs in conformity with Omnicare Guidelines and fax campaigns.

18. With a large patient population base serviced by its pharmacy consultants, Omnicare is in a position to negotiate favorable prices from drug manufacturers. On information and belief, Omnicare can offer more than large volume purchases as an inducement to drug manufacturers to cut their prices—Omnicare can promise that if a drug manufacturer will cut the price for a particular drug below a certain level, Omnicare will make that drug its “preferred” cost effective alternative for certain disease conditions. On information and belief, Omnicare promises that its pharmacy consultants will recommend that physicians switch prescriptions to

the preferred cost alternative drug, allowing Omnicare to promise that its consultants will drive up sales volume in exchange for lower prices. While volume discounts generally fall within the 'safe harbors' to the Anti-Kickback Act, Omnicare's promises to recommend particular drugs through its pharmacy consultants go beyond ordinary volume purchasing decisions, and also constitute violations of the Anti-Kickback Act, because Omnicare is soliciting discounts as a condition for recommending particular drugs to physicians. 42 U.S.C. § 1320A-7b(b)(1) provides:

- (1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind
 - (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
 - (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a crime.

In sum, Omnicare's financial incentive to maximize the spread between acquisition costs and reimbursement levels creates an inherent conflict of interest. Omnicare's consultants serve both as pharmacists and as a highly effective sales force.

19. As an additional inducement for LTCFs to sign pharmacy contracts with Omnicare, Omnicare offered staff services at no cost to provide hemodialysis on-site at LTCF facilities. Omnicare only offered no cost hemodialysis staff to LTCFs that entered into pharmacy contracts with Omnicare.

20. Upon information and belief, Omnicare also followed a practice of falsely and

fraudulently billing for more expensive, name brand drugs when it had actually provided generic versions of those drugs.

21. By requiring its subsidiaries listed in paragraph 4 above, and other subsidiaries unknown to Plaintiff, to follow Omnicare corporate policies and guidelines for recommending particular drugs and billing for name brand drugs when cheaper generic versions had actually been provided, Omnicare has caused its subsidiaries to submit millions of false and fraudulent claims for reimbursement to Medicaid and Medicare.

COUNT I (False Claims Act)
(Pharmacy Consultant Services at Below
Market Rates in Violation of the Anti-Kickback Act)

22. Plaintiff realleges and incorporates by reference paragraphs 2 through 21 as though fully set forth herein.

23. Defendant Omnicare has knowingly submitted false or fraudulent claims for payment, or caused false or fraudulent claims for payment to be submitted, to officials of the United States government, in violation of 31 U.S.C. 3729(a)(1) and (c). Defendant Omnicare knowingly violated the Anti-Kickback Act by offering pharmacy consultant services at below market rates to induce LTCFs to enter contracts for pharmacy services with Omnicare. Once in place through a violation of the Anti-Kickback Act, Omnicare's consultants recommended that physicians switch prescriptions for patients of the LTCFs based at least in part on Omnicare's financial interest in maximizing the spread between acquisition costs and reimbursement levels, which constituted an inherent conflict of interest of the kind that the Anti-kickback Act was designed to prevent. Defendant Omnicare knew that these practices and procedures resulted in fraudulent claims to the federal government through the Medicare and Medicaid programs.

24. Because of the Defendant's conduct set forth above, the United States has suffered actual damages by paying, in many instances, higher reimbursement levels for drugs recommended by Omnicare pharmacy consultants than it would have paid for the drugs previously prescribed for the same patients.

COUNT II (False Claims Act)
(Drug Price Discounts as Inducement for Recommending Drugs as the
Preferred Lower Cost Alternative in Violation of the Anti-Kickback Act)

25. Plaintiff realleges and incorporates by reference paragraphs 2 through 24 as though fully set forth herein.

26. Defendant Omnicare has knowingly submitted false or fraudulent claims for payment, or caused false or fraudulent claims for payment to be submitted, to officials of the United States government, in violation of 31 U.S.C. 3729(a)(1) and (c). Upon information and belief, Defendant Omnicare knowingly violated the Anti-Kickback Act by soliciting price discounts from drug manufacturers in exchange for promises that Omnicare's consulting pharmacists would recommend particular drugs as Omnicare's preferred lower cost alternatives for certain disease conditions. Omnicare's consultants recommended that physicians switch prescriptions for patients of the LTCFs based at least in part on Omnicare's financial interest in maximizing the spread between acquisition costs and reimbursement levels, which constituted an inherent conflict of interest of the kind that the Anti-kickback Act was designed to prevent. Defendant Omnicare knew that these practices and procedures resulted in fraudulent claims to the federal government through the Medicare and Medicaid programs.

27. Because of the Defendant's conduct set forth above, the United States has suffered actual damages by paying, in many instances, higher reimbursement levels for drugs

recommended by Omnicare pharmacy consultants than it would have paid for the drugs previously prescribed for the same patients.

COUNT III (False Claims Act)
(Falsely Submitting Claims for Name Brand Drugs When
Omnicare Actually Provided Cheaper Generic Versions of the Same Drugs)

28. Plaintiff realleges and incorporates by reference paragraphs 2 through 27 as though fully set forth herein.

29. Defendant Omnicare has knowingly submitted false or fraudulent claims for payment, or caused false or fraudulent claims for payment to be submitted, to officials of the United States government, in violation of 31 U.S.C. 3729(a)(1) and (c). Defendant Omnicare submitted, or caused to be submitted, claims to Medicaid and Medicare stating that it had provided more expensive brand name drugs to patients, when in fact, as Omnicare well knew, it had actually provided cheaper generic versions of the same drugs. Defendant Omnicare knew that these practices and procedures resulted in false and fraudulent claims to the federal government through the Medicare and Medicaid programs, because Omnicare was claiming, or causing to be claimed, higher reimbursement levels for those drugs than it or its subsidiaries were really entitled to.

30. Through the conduct described in paragraph 29 above, Defendant Omnicare knowingly made or used, or caused to be made or used, false records or statements to get false or fraudulent claims paid or approved by the officials of the United States government, in violation of 31 U.S.C. §3729(a)(2).

31. Because of the Defendant's conduct set forth above, the United States has suffered actual damages by paying higher reimbursement levels for generic drugs than it should have paid.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Deborah Maguire, acting on behalf of and in the name of the United States, demands and prays that judgment be entered in favor of the United States against Defendant Omnicare, Inc., as follows:

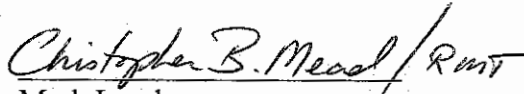
1. For treble the amount of the United States' damages, plus civil penalties of \$10,000 for each false claim;
2. For all costs of this civil action; and
3. For prejudgment interest and for such other and further relief as the Court deems just and equitable.

MOREOVER, Plaintiff Deborah Maguire, on her own behalf, demands and prays that an award be made in her favor as follows: for 25 percent (25%) of the proceeds collected by the United States if the United States intervenes in and conducts this action, or for 30 percent (30%) of the proceeds if the United States does not intervene; for an amount for reasonable expenses necessarily incurred by the relator in the prosecution of this action; for all reasonable attorney's fees and costs incurred by the relator; and such other and further relief to which the relator may show herself justly entitled.

DEMAND FOR JURY TRIAL


Plaintiff Deborah Maguire demands that this case be tried before a jury.

Respectfully submitted,

 Christopher B. Mead / Rmt

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